



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/214,848	01/14/99	SEKINE T	1208/P502PCT

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HM22/1011

EXAMINER
CHOI, F

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Applicant(s) N .

09/214,848

Applicant(s)

SEKINE, TERUAKI

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
 2. ☐ received in Application No. (Series Code / Serial Number) _____.
 3. ☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 20) ☐ Other: _____

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a).

Applicant has changed the title on the specification, in order to adequately identify the Specification a new oath or declaration is required identifying the Specification by the new title. It is suggested that similarly a new small entity declaration and petition for corrected filing receipt be submitted.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ochoa et al. (U.S. Pat. 5,443,983).

Ochoa et al. (U.S. Pat. 5,443,983) expressly discloses a method of developing LAK activity in lymphocytes comprising contacting lymphocytes with IL-2 and an anti-CD3 antibody and a method of administering the same to an AIDS patient falling within the scope of applicant's claims (Column 11, lines 49-68, Column 12, lines 1-50, Claims 1-8).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re May*, 197 USPQ 601, 607 (CCPA 1978). See also *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Alternatively, Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochoa et al. (U.S. Pat. 5,443,983) in view of Rosenberg.

Ochoa et al. (U.S. Pat. 5,443,983) teach a method of developing LAK activity in lymphocytes comprising contacting lymphocytes with IL-2 and an anti-CD3 antibody and a method of administering the same to an AIDS patient (Column 11, lines 49-68, Column 12, lines 1-50, Claims 1-8).

Rosenberg teaches that lymphocytes activated with IL-2 are effective against cancers, viral and other infective diseases, autoimmune diseases, for the correction immune-deficiency diseases, etc. (Column 4, lines 29-54).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose that the activated lymphocytes are effective against viral infections.

However, the prior art amply suggests the same as it is taught lymphocytes activated with IL-2 are effective against viral infections. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use the activated lymphocytes to treat viral infections with the expectation that they would be effective.

Applicant's arguments have been duly considered to the extent they are relative to the new ground of rejection herein but they are deemed unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Applicant argues that the Rosenberg reference does not contain any data or teachings which prove and enable one skilled in the art to make and use activated autologous lymphocytes against viral infections. However, this is not the test for enablement. See MPEP Sections 2164.01 and 2121.01 (even a reference which is non-enabling may be used in a 103 rejection). In any case, contrary to Applicant's argument, as indicated above the Rosenberg does teach that the activated lymphocytes can be used to treat viral infections. Further, Ochoa et al. (U.S. Pat. 5,443,983) teaches a method of administering the same to an AIDS patient. Furthermore, the methods of preparation and administration set forth in Applicant's specification do not appear to

establish that the methods of preparation and administration are unique or distinguishable in the case where a viral infection is treated as opposed to cancer.

Finally, the fact that an article states that lymphocytes prepared using IL-2 were not effective in remedying HIV infections does not appear to be sufficient to overcome the rejection as the prior art does not consist solely of IL-2 but also anti-CD3. Also, the fact that IL-2 activated lymphocytes was disclosed in a reference not to be effective against HIV does not appear to be sufficient evidence that the same would not be effective against viruses in general as it is notoriously well known in the art that HIV is an extremely difficult virus to treat. Examiner reminds Applicant that it is well established patent law that the fact that there may be inoperative embodiments does not necessarily establish that there is a lack of enablement. See MPEP Section 2164.08(b). Applicant herein has claimed the treatment of viruses, as such, in light of the above, the fact that an article discloses that IL-2 activated lymphocytes are not effective against HIV does not appear sufficient to overcome the rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

October 5, 2000


JOHN PAK
PRIMARY EXAMINER
GROUP 1600
